Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 15, 2008 has been entered.

Information Disclosure Statement

The information disclosure statement filed April 17, 2008 fails to comply with 37 CFR 1.98(a) (3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. For this reason, two Japanese patents have not been considered; see the references struck from the enclosed PTO-1449.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 12, 23, 26, 38, 48, 50, 51, 53, 55, and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention. The range of “at least “50:50 alpha tricalcium phosphate:hydroxyapatite” lacks original support in that the range up to 100:0 was not originally contemplated; see the paragraph bridging pages 4 and 5 of the present specification as well as the paragraph bridging pages 12 and 13. Similarly, the range of "at least 666:333" lacks original support.

Claims 1, 12, 23, 26, 38, 48, 50, 51, 53, 55, and 56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the range of 50:50 to 80:20, does not reasonably provide enablement for ratios above 80:20, particularly ratios over 90:10; see the paragraphs bridging pages 4 and 5 and pages 12 and 13 of the present specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Upon review of pages 4, 5, 12, and 13 of the specification, it was not clear how to make the claimed invention at ratios exceeding 80:20 alpha tricalcium phosphate: hydroxyapatite, particularly ratios exceeding 90:10 alpha tricalcium phosphate: hydroxyapatite.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 12, 23, 26, 38, and 47 are rejected under 35 U.S.C. 102(b) as anticipated by Ruys (article entitled "Silicon-doped Hydroxyapatite") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ruys (article entitled "Silicon-doped Hydroxyapatite") alone. Ruys anticipates the claim language where the sol-gel of Ruys is a uniform mixture of hydroxyapatite and silicone which is converted to alpha-TCP by sintering as claimed; see page 71 (the abstract), page 74, last paragraph, and page 76 (the section entitled "Silicon Addition"). Due to the vague language used in the specification pertaining to the basic and novel characteristics, the language "consisting essentially of" has been interpreted as comprising; see MPEP 2111.03 that is incorporated herein by reference. Although not preferred, it was made into a material that was close to a ratio of 50:50 that is within the claimed range; see page 77, lines 15-17. The result of Ruys' process is a bulk material. The concentration of silicone results in primarily alpha-TCP (see page 71 of Ruys), and thus, the Examiner posits that the 50 mol% material of Ruys would inherently result in a primarily alpha-TCP material after sintering.

Furthermore, since the material of Ruys is the same as that claimed, it would inherently be insoluble in physiological fluids and have the same resorbability and *in*

vivo response as claimed because it is the same material as that claimed alpha-tricalcium phosphate; see page 72.

> *The Examiner posits that the effective filing date of the present claims is August 30, 1996 because the provisional application 60/003,157 and the earlier parent application 08/576,238 only disclosed silicon entities and not other types of entities as the present claims do. Therefore, the present claims have a later filing date because the term stabilization or the meaning of stabilization entities was broadened from the meaning it had in the parent application filed before August 30, 1996.

Alternatively, one may not consider Ruys as meeting the claim language because the disclosure of the amounts of components is not analyzed in detail, and Ruys prefers low dopant levels to avoid tricalcium phosphate (i.e. TCP) and the associated biodegradability. However, since low dopant levels are only preferred and the concept of high dopant levels is also disclosed, the Examiner asserts that it would have been at least obvious to make higher dopant materials that would fall within the claimed range when a more biodegradable material was desired.

With regard to claim 12, the material of Ruys is the same as that claimed and disclosed, and thus, it inherently has the same solubility properties such that this claim language is fully met.

With regard to claim 26, Ruys fails to disclose the particle size as claimed even though it was disclosed as being crushed and pelletized; see page 76. However, since it was known, in the art, to crush and pelletize the same material as claimed, it is the Examiner's position that the mere selection of a particle size would have been considered prima facie obvious to an ordinary artisan because it has not shown to provide some advantage, solve some stated problem or used

for some particular purpose, the Examiner takes the position that it would have been considered prima facie obvious to use the claimed particle size with the Ruys composition; see MPEP 2144.04.

> In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Claims 48 to 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruys (article entitled "Silicon-doped Hydroxyapatite") alone. Ruys discloses materials where the TCP content is slightly greater than the hydroxyapatite content; see page 77, lines 15-17. However, since low dopant levels are only preferred and the concept of high dopant levels is also disclosed, the Examiner asserts that it would have been clearly obvious to make higher dopant materials that would fall within the claimed range when a more biodegradable material was desired.

Claims 1, 12, 38, 47-53, 55, and 56 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies (WO 94/26872). Davies anticipates the claim language where alpha tricalcium phosphate is formed from HA by sintering at temperatures from 800 0C to 1100 0C; see page 7, line 24 to page 8, line 27 and page 27, line 11 et seq. The stabilizing entity as claimed is silicon from the quartz substrate because quartz is SiO2. Since the ratio of tricalcium phosphate to hydroxyapatite can be up to 90:10, the claimed ranges are considered clearly met.

With regard to claim 12, the material produced by Davies is inherently insoluble to the extent claimed because it is the same material as that claimed.

Response to Arguments

Applicant's arguments filed April 15, 2008 have been fully considered but they are not persuasive.

On page 6 of the response, the Applicant's remarks pertaining to the claimed range of 50:50 to 80:20 is noted. However, the claimed range over 80:20 does not have original support in that the Applicant only appears to have originally contemplated a range stretching from 50:50 to 80:20; see the new Section 112, first paragraph rejections and the paragraphs bridging pages 4-5 and 12-13.

On page 9 of the response, the Applicant argues that "consisting essentially of" precludes Si-P-O glass as disclosed as present in Ruys. However, it is noted that "consisting essentially of" does not preclude other calcium phosphate phases (see page 9, line 24 to page 10, line 20) or other contaminants (see page 12, lines 9-19). Furthermore, the basic and novel characteristic is that the alpha tricalcium phosphate not be soluble in physiological fluids as provided by the stabilization. In particular, page 12 of the present specification states that the contaminant "**preferably** does not affect the composition and morphology of the stabilized composition in any manner which will affect the support of bone cell activity thereon." (emphasis added) This sort of vague language suggests that the amount of bone cell activity is merely a preference. For this reason, the claim language "consisting essentially of" has been interpreted as having the same scope a comprising; see MPEP 2111.03.

Moreover, according to the sintering reaction, for every mole of hydroxyapatite, a half mole of silicon is needed to react with the CaO that is formed; see page 13, line 11

of the specification. This is equal to 40% (for (80:20) to 25% (for 50:50) of the amount of hydroxyapatite utilized in the reaction. Since these amounts are well above the 20% limit suggested by the declaration filed November 2, 2007, the claimed composition would also contain silicon to the extent that it would affect the basic and novel characteristics of the composition.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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